K071032

AUG 20 2007

4 510(k) Summary of Safety and Effectiveness

Manufacturer	Arthrex Med. Inst. GmbH Liebigstrasse 13 D-85757 Karlsfeld/München Germany
Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Nancy Hoft Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1113 Fax: 239/598.5508 Email: nancy.hoft@arthrex.com
Trade Name	Arthrex Univers II Shoulder Prosthesis
Common Name	Shoulder Prosthesis
Product Code - Classification Name	**KWS** – Prosthesis, Shoulder, semi constrained metal/polymer, cemented **HSD** – Prosthesis, Shoulder, hemi-humeral, metal, uncemented
Predicate Device	Arthrex Shoulder Prosthesis (Univers Shoulder), K010124
Device Description and Intended Use	The Arthrex Univers II Shoulder Prosthesis consists of a stem for attachment to the humerus, a spherical head for replacing the humeral head, and a trunnion construct to connect the stem to the spherical head. The modified device is identical to the cleared predicate (K010124) except for how it addresses two of the three key angles that can be adapted to match the geometry of the humeral head. The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional

	arthroplasty is not acceptable. The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.
Substantial Equivalence Summary	The Arthrex Univers II Shoulder Prosthesis is substantially equivalent to the predicate Arthrex Univers Shoulder Prosthesis in which the basic features and intended uses are the same. Any differences between the Arthrex Univers II Shoulder Prosthesis and the predicate Arthrex Univers Shoulder Prosthesis are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Arthrex Univers II Shoulder Prosthesis is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 2007

Arthrex, Inc.
% Ms. Nancy Holt
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, FL 34108-1945

Re: K071032
Trade/Device Name: Arthrex Univers II Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal-polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS, HSD
Dated: July 20, 2007
Received: July 23, 2007

Dear Ms. Holt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucknap
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number: _____

Device Name: **Arthrex Univers II Shoulder Prosthesis**

The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.

The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Marlene Brenno

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071032